



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DATE OUT: March 5, 2019

SUBJECT: STORAGE STABILITY (830.6317) & CORROSION CHARACTERISTICS
(830.6320) REVIEW
ACCELERATED STUDY ☒; ONE YEAR STUDY ☐;
OVER 1 YEAR STUDY ☐
MP ☐ EP ☒ EUP ☐
DP BARCODE No.: 449128 REG. No.: 2724-842
DECISION No.: 543733 MRID No(s): 506566-01
PRODUCT NAME: RF2236 CDSO-N1 FOR DOGS
COMPANY: WELLMARK INTERNATIONAL

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I. CONCLUSIONS:

STORAGE STABILITY (830.6317):
☒ ACCEPTABLE
☐ UNACCEPTABLE*
☐ UPGRADEABLE*

40CFR158.190 DATA REQUIREMENT: ☒ SATISFIED ☐ NOT SATISFIED

CORROSION CHARACTERISTICS (830.6320):
☒ ACCEPTABLE
☐ UNACCEPTABLE*
☐ UPGRADEABLE*

40CFR158.190 DATA REQUIREMENT: ☒ SATISFIED ☐ NOT SATISFIED

* If unacceptable or upgradeable describe the deficiency and provide recommendations

Comments & Recommendations:

One lot of RF2236 CDSO-N1 was tested for stability at elevated temperature. It was assayed initially to verify that the product was within specification. The samples were stored for two weeks at 54°C in the commercial containers in accordance with the EPA Storage Stability at Elevated Temperature procedure. Final assays were then performed to verify that no significant change in active ingredients had occurred.

The initial assay was within specification and had no significant change of active ingredient level after two weeks of elevated temperature storage. This demonstrates the product's chemical stability under the elevated temperature guidelines.

No changes in the color odor, or physical state of the product were observed, and there was no physical degradation or other evidence of corrosion to the package after two weeks of elevated temperature storage.

II. STUDY SUMMARY

A. STUDY CONDUCTED UNDER US GLP/OECD GUIDELINES

☒ Yes

☐ No

B. PRODUCT INFORMATION

Active ingredient(s): ETO; PBO; MGK; Nylar

Label claim(s) Nominal concentration(s) (%): 55.0; 10.0; 1.0; 0.5

Initial concentration(s) of the AI(s) (%) used in the study: 55.23; 10.12; 0.99; 0.52

Lower certified limits (%) based on AI % in the label: 53.35; 6.5; 0.9; 0.45

Lower certified limits (%) based on AI % in the study: 53.5731; 9.614; 0.891; 0.468

C. EXPERIMENTAL PARAMETERS

Temperature: ☐ Freezer; Room ☐; Warehouse ☒; 54°C ☐; Other ☐

Humidity: Indicate 25°C / 50% (if provided)

Duration of study: ☒ 2 weeks; ☐ 1 year; ☐ over 1 year

Type of container: ☐ Glass; ☐ Metal; ☐ HDPE; ☐ Fluorinated HDPE; ☐ Other

Analysis at intervals: ☒ 0 (initial);

☐ 3 months; ☐ 6 months

☐ 9 months; ☐ 12 months

☐ Over 12 months

D. ANALYTICAL METHOD

Method	DETECTOR
Gas chromatography (GC)	<input checked="" type="checkbox"/> FID (Flame Ionization Detector) <input type="checkbox"/> ECD (Electron Capture Detector) <input type="checkbox"/> N/P (Nitrogen/Phosphorous Detector) <input type="checkbox"/> Other
Capillary Gas chromatography (CGC)	<input type="checkbox"/> FID (Flame Ionization Detector) <input type="checkbox"/> ECD (Electron Capture Detector) <input type="checkbox"/> N/P (Nitrogen/Phosphorous Detector) <input type="checkbox"/> Other
High Pressure Liquid chromatography (HPLC)	<input type="checkbox"/> UV/VIS (nm) <input type="checkbox"/> RI (Refractive Index) <input type="checkbox"/> Other
GC-MS / LC-MS	Specify
Other	Specify

E. RESULTS

Initial data point at warehouse storage

Lot #	w/w % ETO	w/w % PBO	w/w % MGH 264	w/w % Nylar ®	Package Appearance	Physical Appearance
HN518.61	55.23	10.12	0.99	0.52	NVA	NVA

Fourteen (14) day data point at 54°C

Lot #	w/w % ETO	w/w % PBO	w/w % MGH 264	w/w % Nylar ®	Package Appearance	Physical Appearance
HN518.61	54.66	10.01	0.99	0.52	NVA	NVA